

**Department of State Health Services**  
**Agenda Item for State Health Services Council**  
**May 5, 2005**

**Agenda Item Title:** New, Repeals, and Amendments to Rules Relating to Minimum Standards for the Licensing and Operation of Ambulatory Surgical Centers.

**Agenda Number:** 5i

**Recommended Council Action:**

☐ For Discussion Only

☒ For Discussion and Action by the Council

**Background:**

The licensing rules for Ambulatory Surgical Centers establish the licensing procedures, standards for operation, and requirements concerning construction design and the life safety code. Rules governing the operation of Ambulatory Surgical Centers have been in effect since 1986.

**Summary:**

Sections of the rules that have been repealed and proposed as new will reorganize, clarify and add new requirements related to providing anesthesia and surgical services, minimum staffing, and the reporting of incidents and other information to the department. Proposed amendments include clarification related to implementation of the 2-year renewal cycle for licenses, adds wording regarding the department's authority to collect fees related to application processing through the Texas Online Authority, adds and expands definitions of several terms, including length of stay limitations, provides for the use of flammable germicides for surgical site preparation and updates the enforcement section to be consistent with other facility licensing rules.

**Summary of Stakeholder Input to Date (including advisory committees):**

All licensed Ambulatory Surgical Centers, as well as the Texas Hospital Association, the Texas Medical Association, the Texas Nurses Association and the Texas Ambulatory Surgical Association, received draft copies of the rules in July 2004, and were given an opportunity to provide input. Stakeholder comments and suggestions were considered and appropriate changes were incorporated.

**Proposed Motion:** Motion to recommend HHSC approval for publication of rules contained in agenda item #5i.

**Presented by:** Cindy Bednar

**Approved by:** Rick Bays

**Date Submitted**

**Title:** Manager, Facility Licensing Group

**Contact:** Cindy Bednar

03/16/05

**Program/Division:** Regulatory Services

## Title 25. Health Services

### Part 1. Department of State Health Services

#### Chapter 135. Ambulatory Surgical Centers

##### Subchapter A. Operating Requirements for Ambulatory Surgical Centers

Amendments §§135.1-135.4, 135.9, 135.10, 135.14, 135.18-135.25

Repeal §§135.11, 135.15, 135.26

New §§135.11, 135.15, 135.26, 135.29

##### Subchapter B. Safety Requirements for New and Existing Ambulatory Surgical Centers

Amendments §§135.41, 135.42

##### Subchapter C. Physical Plant and Construction Requirements for New and Existing Ambulatory Surgical Centers, Amendment §135.52

### Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes amendments to §§135.1-135.4, 135.9, 135.10, 135.14, 135.18-135.25, 135.41, 135.42 and 135.52, the repeal of §§135.11, 135.15 and 135.26, and new §§135.11, 135.15, 135.26 and 135.29, concerning the regulation of ambulatory surgical centers.

### BACKGROUND AND PURPOSE

The amendments, repeals, and new sections are proposed in accordance with Health and Safety Code (HSC), Chapter 243, which charges the department with the responsibility to license ambulatory surgical centers. The amendments, repeals, and new sections are necessary to comply with Government Code, Chapter 2054, Subchapter K, which requires the department to participate in an electronic system for occupational licensing transactions (Texas Online); Acts, 2003, 78th Legislature, Regular Session, Chapter 198, (House Bill 2292), §2.42, added Health and Safety Code, §12.0111, which requires the department to charge a fee sufficient to cover the cost of administering and enforcing the licensing program; and Health and Safety Code, §12.0112, which requires that the term for licenses issued or renewed after January 1, 2005, will be two years, Texas Government Code, Chapter 2005, which requires state agencies to adopt procedural rules for processing permit applications; and as a response to a request by stakeholders for clarification of certain provisions of the rules.

### SECTION-BY-SECTION SUMMARY

The amendments to §§135.1, 135.14 and 135.18 - 135.22, 135.25, and 135.41 update and correct references within the sections. The proposed amendment to §135.2 adds definitions for “premises” and “extended observation”, updates and clarifies the definitions of “advanced practice nurse”, “ambulatory surgical center”, “available”, “licensed vocational nurse” and “registered nurse”, and deletes the definition of “director” which is deemed unnecessary. The amendment to §135.3 clarifies that the fee for a one-year license is doubled when a license is issued for a two-year period. Department rules for the issuance of two-year licenses beginning January 1, 2005, became effective on April 4, 2004. Wording is also added to the section concerning the department’s authorization to collect subscription and convenience fees, in amounts to be determined by the Texas Online Authority, to recover costs associated with application and renewal application processing. The amendment to §135.4 requires the ASC governing body to adopt, implement and enforce policies relating to accurate billing for services and supplies and for compliance with the Texas Insurance Code. The amendment to §135.9 requires an evaluation of nutritional needs when a patient is in the ASC more than eight hours. The amendment to §135.10 adds a requirement for an emergency call system. The amendment to §135.23 clarifies the physical location or premises the ASC license covers. The amendment to §135.24 is to make the enforcement section language the same as other facility licensing rules. The amendment of §135.42 allows flammable germicides to be used for preoperative surgical skin preparation under specified conditions,

establishes a requirement for the ASC to report surgical suite fires to the department within two business days and to implement a corrective action plan within 30 days. The amendment to §135.52 updates language to reflect current terminology used in other guidelines and standards and updates references for patient spaces.

The sections proposed for repeal address anesthesia and surgical services, nursing services, and reporting of incidents. The proposed new §§135.11, 135.15 and 135.26 reflect reorganization of existing sections and contain new language to clarify the requirements for providing anesthesia and surgical services, nursing services, and reporting requirements. New §135.11 identifies anesthesia that a hospital's governing body may approve for use in the ASC including the equipment and supply needs for each; requires compliance with the American Society of Anesthesiologists guidelines and standards; and requires that a physician shall be on call and able to respond physically or by telephone within 30 minutes until all patients have been discharged. New §135.15 requires a registered nurse with certification in basic cardiac life support to be on duty and on the premises whenever patients are in the facility, and establishes staffing requirements for the particular anesthesia to be administered. New §135.26 establishes specific incidents that must be reported to the department within 10 business days, and data that the ASC must provide annually on a form prescribed by the department. New §135.29 provides time periods for processing application for initial and renewal licenses.

#### FISCAL NOTE

Cindy Bednar, Manager, Facility Licensing Group, has determined that for each year of the first five years the sections are in effect, there will be no fiscal implications to state or local government as a result of administering the sections as proposed.

#### SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

**Ms. Bednar has determined that there will be costs to small businesses, micro-businesses or persons who are required to comply with the sections as proposed. These costs will be related to the department's collection of subscription and convenience fees from applicants and licensees, in amounts to be determined by the Texas Online Authority. There will be no anticipated impact on local employment.**

#### PUBLIC BENEFIT

In addition, Ms. Bednar has also determined that for each year of the first five years the sections are in effect, the public benefit anticipated as a result of enforcing or administering the sections will be to allow greater flexibility for patients to receive services in ambulatory surgical centers while maintaining minimum standards for safe patient care.

#### REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environment exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environment exposure.

#### TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments, repeals, and new sections do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

## PUBLIC COMMENT

Comments on the proposal may be submitted to Cindy Bednar, Manager, Facility Licensing Group, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, (512) 834-6648 or by email to [Cindy.Bednar@dshs.state.tx.us](mailto:Cindy.Bednar@dshs.state.tx.us). Comments will be accepted for 60 days following publication of this proposal in the *Texas Register*.

## STATUTORY AUTHORITY

The proposed amendments, repeal and new sections are authorized under Health and Safety Code, §243.009, concerning rules and minimum standards to protect and promote the public health and welfare by providing for the issuance, renewal, denial, suspension, and revocation of each license; Health and Safety Code, §12.0111, which requires the department to charge fees for issuing or renewing a license; §12.0112, which requires the term of each license issued to be two years; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules reasonably necessary for the department to administer its regulatory and administrative functions.

The proposed amendments, repeal, and new sections affect the Health and Safety Code, Chapters 243 and 1001, and Government Code, Chapter 531.

Sections for repeal.

§135.11. Anesthesia and Surgical Services.

§135.15. Nursing Services.

§133.26. Reporting of Incidents.

Legend: (Proposed Amendments.)

Single Underline = Proposed new language

**[Bold Print and Brackets]** = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

#### §135.1. Scope and Purpose.

(a) The purpose of these sections is to implement Health and Safety Code, Chapter 243 which requires ambulatory surgical centers to be licensed by the **[Texas]** Department of State Health Services.

(b) – (c) (No change.)

#### §135.2. Definitions.

**The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.**

(1) – (3) (No change.)

**(4) Advanced Practice Nurse (APN)--A registered [professional] nurse, currently licensed in the State of Texas, who has been approved by the Board of Nurse Examiners for the State of Texas (board) to practice as an advanced practice nurse based on completing an advanced educational program of study acceptable to the board. The term includes a nurse practitioner, nurse-midwife, nurse anesthetist, and a clinical nurse specialist** [is prepared for advanced nursing practice by virtue of knowledge and skills obtained in an advanced educational program of study acceptable to the board, who meets requirements of Rule 221 and/or Rule 222 as defined by the Texas Board of Nurse Examiners, and has received authorization to practice as an APN in Texas].

(5) (No change.)

**(6) Ambulatory Surgical Center (ASC)--A facility that [operates] primarily provides [to provide] surgical services to patients who do not require overnight hospitalization or extensive recovery, convalescent time or observation [hospital care]. The planned total length of stay for an ASC patient shall not exceed 23 hours. Patient stays of greater than 23 hours must be the result of an unanticipated medical condition and shall occur infrequently. The 23-hour period begins with the induction of anesthesia.**

(7) (No change.)

**(8) Available--Able to be physically present in the facility to assume responsibility for the delivery of patient care services within five minutes.** [On the premises and sufficiently free from other duties to enable the individual to respond rapidly to emergency situations.]

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(9) – (11) (No change.)

(12) Department--The [Texas] Department of State Health Services.

**[(13) Director--The director of the Health Facility Licensing and Compliance Division of the Texas Department of Health or his or her designee.]**

(13) [(14)] Disposal--The discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste (whether containerized or uncontainerized) into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharge into any waters, including ground waters.

(14) [(15)] Electronic Signature--Signature produced or generated on a computer.

(15) Extended observation--The period of time that a patient remains in the facility following recovery from anesthesia and discharge from the post anesthesia care unit, during which additional comfort measures or observation may be provided.

(16) – (17) (No change.)

(18) Licensed vocational nurse (LVN)--A person who is currently licensed under the Nursing Practice Act by the Board of Nurse Examiners for the State of Texas **[the laws of this state to use the title,]** as a licensed vocational nurse or who holds a valid vocational nursing license with multi-state licensure privilege from another compact state.

(19) – (22) (No change.)

(23) Premises--A building where patients receive outpatient surgical services.

**(24) [(23)] Prescriber--A person who is legally authorized to write an order or prescription for a health care service, medical device, or drug.**

**(25) [(24)] Registered nurse (RN)--A person who is currently licensed by the Board of Nurse Examiners for the State of Texas [under the laws of this state] as a registered nurse or who holds a valid registered nursing license with multi-state licensure privilege from another compact state.**

(26) [(25)] Root cause analysis--An interdisciplinary review process for identifying the basic or contributing causal factors that underlie a variation in performance associated with an adverse event or reportable event as listed under §135.27 of this title (relating to Patient Safety Program). It focuses primarily on systems and processes, includes an analysis of underlying cause and effect, progresses from special causes in clinical processes to

### §§135.2, 135.3

common causes in organizational processes, and identifies potential improvements in processes or systems.

(27) [(26)] Title XVIII--Title XVIII of the United States Social Security Act, 42 U.S.C. §1395 et seq.

#### §135.3. Fees.

(a) Initial license fee. The fee for an initial license (includes change of ownership or relocation) is \$4,000. The license term is two years. **[(a) The Texas Board of Health has established the following schedule of fees for licensure as an ASC:]**

[(1) initial/relocation license fee--\$2,000.]

[(2) renewal license fee--\$2,000.]

[(3) change of ownership license fee--\$2,000.]

#### (b) Renewal license fee.

(1) The fee for renewal licenses issued through December 31, 2005, will be either \$2000 for a one-year license, or \$4000 for a two-year license. The department will determine the license term and notify the ASC prior to the license renewal date.

(2) The fee for a renewal license issued January 1, 2006, and after will be \$4,000. The license term will be two years.

(c) [(b)] Official submission. The department will not consider an application as officially submitted until the applicant pays the application fee and submits the application form. **[The fee must accompany the application form.]**

(d) [(c)] Nonrefundable. Fees paid to the department are not refundable.

(e) [(d)] Payment of fees. All fees shall be paid to the **[Texas]** Department of State Health Services.

(f) [(e)] Fee schedule review. The department **[board]** shall make periodic reviews of its fee schedule and make any adjustments necessary to provide funds to meet its expenses without creating an unnecessary surplus. Such adjustments shall be through section amendments.

(g) Other fees. The department is authorized to collect subscription and convenience fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through Texas Online, in accordance with Texas Government Code, §2054.111.

**§§135.4, 135.9, 135.10**

§135.4. ASC Operation.

(a) - (i) (No change.)

(j) The governing body shall adopt, implement and enforce a written policy to ensure accurate billing for services and supplies. The policy shall include a procedure for addressing complaints related to billed services and supplies.

(k) The governing body shall adopt, implement and enforce a policy requiring compliance with the Texas Insurance Code, Article 21.24-1 (relating to Assignment of Health Care Benefit Payments).

(l) [(j)] Informed consent for abortion. An ASC that performs abortions shall adopt, implement and enforce a policy to ensure compliance with Health and Safety Code, Chapters 171 and 245, Subchapters A and B (relating to Abortion and Informed Consent).

§135.9. Medical Records.

(a) - (i) (No change.)

(j) The ASC record shall include the following:

(1) - (9) (No change.)

(10) evidence of evaluation of the patient by a physician or advanced practice nurse prior to dismissal; **[and]**

(11) evidence that the patient was dismissed in the company of a responsible adult unless a physician or advanced practice nurse writes an order that the patient may be dismissed without the company of a responsible adult; and [.]

(12) for patients with a length of stay greater than eight hours, an evaluation of nutritional needs and evidence of how identified needs were met.

(k) – (q) (No change.)

§135.10. Facilities and Environment.

(a) The ASC shall have the necessary personnel, equipment, and procedures to handle medical emergencies that may arise in connection with services sought or provided. At a minimum, the ASC shall provide:

(1) - (2) (No change.)

(3) a comprehensive emergency plan to address internal and external emergencies, including:



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(A) – (B) (No change.)

(C) a requirement for at least four drills a year of the internal emergency plan. [; and]

**[(4) personnel trained in cardiopulmonary resuscitation and the use of emergency equipment present in the facility during hours of operation.]**

(b) – (c) (No change.)

(d) An emergency call system shall be provided and readily accessible to staff and patients in all areas of the facility. **[(d) Appropriate emergency equipment and supplies shall be maintained and readily accessible to all areas of each building and shall include the following:]**

**[(1) emergency call system;]**

**[(2) oxygen;]**

**[(3) mechanical ventilatory assistance equipment, including airways and manual breathing bag;]**

**[(4) cardiac defibrillator;]**

**[(5) cardiac monitoring equipment;]**

**[(6) laryngoscopes and endotracheal tubes;]**

**[(7) functioning suction equipment; and]**

**[(8) emergency drugs and supplies specified by the medical staff.]**

(e) - (h) (No change.)

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Legend: (Proposed New Rule)

Regular Print = Proposed new language

### §135.11. Anesthesia and Surgical Services.

#### (a) Anesthesia services.

(1) Anesthesia services provided in the ASC shall be limited to those that are approved by the governing body, which may include the following.

(A) Topical anesthesia--an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce transient and reversible loss of sensation to the circumscribed area.

(B) Local anesthesia--administration of an agent that produces a transient and reversible loss of sensation to a circumscribed portion of the body.

(C) Regional anesthesia - injection of an anesthetic agent to the nerves supplying a region of the body that results in a loss of sensation.

(D) Minimal sedation (anxiolysis)--a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

(E) Moderate sedation/analgesia ("conscious sedation")--a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained (reflex withdrawal from a painful stimulus is NOT considered a purposeful response).

(F) Deep sedation/analgesia--a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. (Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.)

(G) General anesthesia--a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

(2) Anesthesia services shall be under the direction of a physician approved by the governing body upon the recommendation of the ASC medical staff.

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(3) The medical staff will develop and enforce written practice guidelines and standards for the administration of anesthesia.

(A) Administration of anesthesia shall follow the applicable American Society of Anesthesiologists guidelines and standards, including:

- (i) Basic Standards for Preanesthesia Care;
- (ii) Standards for Basic Anesthetic Monitoring;
- (iii) Standards for Postanesthesia Care; and
- (iv) Guidelines for Ambulatory Anesthesia and Surgery.

(B) If the provisions contained in the guidelines listed in subparagraph (A) of this paragraph conflict with this section, the provisions of this section supersede.

(C) Copies of the standards and guidelines are available for review at the Department of State Health Services, Facility Licensing Group, Exchange Building, 8407 Wall Street, Austin, Texas 78754. Copies may also be obtained by writing the American Society of Anesthesiologists, 520 North Northwest Highway, Park Ridge, Illinois 60068-2573; Internet [www.asahq.org](http://www.asahq.org); or by telephone at (847) 825-5586.

(4) Anesthesia must be administered only by:

(A) an anesthesiologist;

(B) a physician, dentist, oral surgeon or podiatrist who is qualified under state law and has education, training and experience in the type of anesthesia being performed; or

(C) a certified registered nurse anesthetist who is under the supervision, as defined by the Medical Practice Act, Texas Occupations Code, §157.058, and the Nurse Practice Act, Texas Occupations Code, §301.152, of the operating physician or of an anesthesiologist who is immediately available if needed

(D) a qualified professional nurse, under the direct supervision of the physician, may administer those types of anesthesia that the Board of Nurse Examiners for the State of Texas has determined are within the scope of practice for a registered nurse. If a registered nurse administers anesthesia in the facility, the facility must:

(i) verify that the registered nurse has the requisite training, education and experience to administer the anesthesia;

(ii) maintain documentation to support that the registered nurse has demonstrated competency in the administration of the anesthesia;

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(iii) with input from the facility's qualified anesthesia providers, develop, implement and enforce detailed, written policies and procedures to guide the registered nurse; and

(iv) ensure that the registered nurse has no other duties except to monitor the patient during the administration of the anesthesia and the procedure.

(5) Anesthesia shall not be administered unless the operating surgeon or anesthesiologist has evaluated the patient immediately prior to surgery to assess the risk of the anesthesia relative to the surgical procedure to be performed.

(6) The anesthesiologist or the operating physician shall be available until all of his or her patients operated on that day have been discharged from the post-anesthesia care unit.

(7) Patients who have received anesthesia shall be evaluated for proper anesthesia recovery by the operating surgeon or the person administering the anesthesia prior to discharge from the post-anesthesia care unit using criteria approved by the medical staff.

(8) Patients who remain in the facility for extended observation following discharge from the post-anesthesia care unit shall be evaluated immediately prior to discharge from the facility by a physician, the person administering the anesthesia or a registered nurse, in accordance with written policies and procedures of the medical staff to include criteria developed by the medical staff for post-operative monitoring of anesthesia.

(9) A physician shall be on call and able to respond physically or by telephone within 30 minutes until all patients have been discharged from the ASC.

(10) Emergency equipment and supplies appropriate for the type of anesthesia services provided shall be maintained and accessible to staff at all times.

(A) Functioning equipment and supplies which are required for all facilities include:

(i) suctioning equipment, including a source of suction and suction catheters in appropriate sizes for the population being served;

(ii) source of compressed oxygen;

(iii) basic airway management equipment, including oral and nasal airways, face masks, and self-inflating breathing bag-valve set;

(iv) blood pressure monitoring equipment; and

(v) emergency medications specified by the medical staff and appropriate to the type of surgical procedures and anesthesia services provided by the facility.

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(B) In addition to the equipment and supplies required under subparagraph (A) of this paragraph, facilities which provide moderate sedation/analgesia, deep sedation/analgesia, regional analgesia and/or general anesthesia must provide the following:

(i) intravenous equipment, including catheters, tubing, fluids, dressing supplies, and appropriately sized needles and syringes;

(ii) advanced airway management equipment, including laryngoscopes and an assortment of blades, endotracheal tubes and stylets in appropriate sizes for the population being served;

(iii) a mechanism for monitoring blood oxygenation, such as pulse oximetry;

(iv) electrocardiographic monitoring equipment;

(v) cardiac defibrillator; and

(vi) pharmacologic antagonists as specified by the medical staff and appropriate to the type of anesthesia services provided.

(b) Surgical services.

(1) Surgical procedures performed in the ASC shall be limited to those procedures that are approved by the governing body upon the recommendation of qualified medical personnel.

(2) Adequate supervision of surgery conducted in the ASC shall be a responsibility of the governing body, shall be recommended by qualified medical personnel, and shall be provided by appropriate personnel.

(3) Surgical procedures shall be performed only by health care practitioners who are licensed to perform such procedures within Texas and who have been granted privileges to perform those procedures by the governing body of the ASC, upon the recommendation of qualified medical personnel and after medical review of the practitioner's documented education, training, experience, and current competence.

(4) Surgical procedures to be performed in the ASC shall be reviewed periodically as part of the peer review portion of the ASC's quality assurance program.

(5) An appropriate history, physical examination, and pertinent preoperative diagnostic studies shall be incorporated into the patient's medical record prior to surgery.

(6) The necessity or appropriateness of the proposed surgery, as well as any available alternative treatment techniques, shall be discussed with the patient prior to scheduling the patient for surgery.

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**(7) Licensed nurses and other personnel assisting in the provision of surgical services shall be appropriately trained and supervised and shall be available in sufficient numbers for the surgical care provided.**

**(8) Each operating room shall be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all persons in the area.**

(A) If flammable agents are present in an operating room the room shall be constructed and equipped in compliance with standards established by the National Fire Protection Association (NFPA 99, Annex 2, Flammable Anesthetizing Locations, 1999) and with applicable state and local fire codes.

**(B) If nonflammable agents are present in an operating room the room shall be constructed and equipped in compliance with standards established by the National Fire Protection Association (NFPA 99, Chapters 4 and 8, 1999) and with applicable state and local fire codes.**

(9) With the exception of those tissues exempted by the governing body after medical review, tissues removed during surgery shall be examined by a pathologist, whose signed report of the examination shall be made a part of the patient's medical record.

(10) A description of the findings and techniques of an operation shall be accurately and completely written or dictated immediately after the procedure by the health care practitioner who performed the operation. If the description is dictated, an accurate written summary shall be immediately available to the health care practitioners providing patient care and becomes a part of the patient's medical record. Refer to §135.9(p) of this title (relating to Medical Records).

(11) A safe environment for treating surgical patients, including adequate safeguards to protect the patient from cross-infection, shall be assured through the provision of adequate space, equipment, and personnel.

(A) Provisions shall be made for the isolation or immediate transfer of patients with communicable diseases.

(B) All persons entering operating rooms shall be properly attired.

(C) Acceptable aseptic techniques shall be used by all persons in the surgical area.

(D) Only authorized persons shall be allowed in the surgical area.

(E) Suitable equipment for rapid and routine sterilization shall be available to assure that operating room materials are sterile.

(F) Environmental controls shall be implemented to assure a safe and sanitary environment.

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(G) Operating rooms shall be appropriately cleaned before each operation.

(12) Written policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies shall be developed, implemented and enforced. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items (reusable items), as well as for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment.

(A) Policies and procedures shall be developed following standards, guidelines and recommendations issued by the Association of Operating Room Nurses (AORN), the Association for Professionals in Infection Control and Epidemiology (APIC), the Centers for Disease Control and Prevention (CDC) and, if applicable, the Society of Gastroenterology Nurses and Associates (SGNA). Standards, guidelines, and recommendations of these organizations are available for review at the Department of State Health Services, Exchange Building, 8407 Wall Street, Austin, Texas. Copies may also be obtained directly from each organization, as follows: AORN, 2170 South Parker Road, Suite 300, Denver CO, 80231, (800) 755-2676; APIC, 1275 K Street, NW, Suite 1000, Washington, DC, 20005, (202) 789-1890; CDC, National Center for Infectious Disease, Mailstop C-14, 1600 Clifton Road, Atlanta, GA, 30333; SGNA, 401 North Michigan Avenue, Chicago, IL, 60611.

**(B) Policies and procedures shall also address proper use of external chemical indicators and biological indicators.**

(C) Performance records for all sterilizers shall be maintained for a period of 6 months.

(D) Preventive maintenance of all sterilizers shall be completed according to manufacturers recommendations on a scheduled basis. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least one year and shall be available for review to the facility within two hours of request by the department.

(13) Emergency power adequate for the type of surgery performed shall be available in the operative and post operative recovery areas.

(14) Periodic calibration and/or preventive maintenance of all equipment shall be provided in accordance with manufacturer's guidelines.

(15) The informed consent of the patient or, if applicable, of the patient's legal representative, shall be obtained before an operation is performed.

(16) A written procedure shall be established for observation and care of the patient during the preoperative preparation and postoperative recovery period.

(17) Written protocols shall be established for instructing patients in self-care after surgery, including written instructions to be given to patients who receive conscious sedation, regional and general anesthesia.

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(18) Patients who have received anesthesia shall be dismissed in the company of a responsible adult unless a physician or advanced practice nurse writes an order that the patient may be dismissed without the company of a responsible adult.

(19) An effective written procedure for the immediate transfer to a hospital of patients requiring emergency care beyond the capabilities of the ASC shall be developed. The ASC must have a written transfer agreement with a hospital or all physicians on staff at the ASC must have admitting privileges at a local hospital.



## §135.14

Legend: (Proposed Amendments.)

Single Underline = Proposed new language

**[Bold Print and Brackets]** = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

### §135.14. Radiology Services.

(a) - (f) (No change.)

(g) Policies shall address the safety aspects of radiology services, including, but not limited to:

(1) regulation of the use, removal, handling, and storage of any radioactive material which is required to be licensed by the **[Texas]** Department of State Health Services, **[Bureau of]** Radiation Control;

(2) - (6) (No change.)

(h) Laser equipment shall be licensed as required by the **[Texas]** Department of State Health Services, **[Bureau of]** Radiation Control. Policies and procedures shall be established and implemented for laser technology which include laser safety programs, education and training of laser personnel, credentialing for each specific laser and a requirement for all personnel working with lasers to be adequately trained in the safety and use of each type of laser utilized.

## §135.15

Legend: (Proposed New Rule)

Regular Print = Proposed new language

### §135.15. Facility Staffing and Training.

#### (a) Nursing services.

(1) There shall be an organized nursing service under the direction of a qualified registered nurse (RN). The ASC shall be staffed to assure that the nursing needs of all patients are met.

(2) There shall be a written plan of administrative authority for all nursing services with responsibilities and duties of each category of nursing personnel delineated and a written job description for each category. The scope of nursing service shall include, but is not limited to, nursing care rendered to patients preoperatively, intraoperatively, and postoperatively.

(A) The responsible individual for nursing services shall be a qualified RN whose responsibility and authority for nursing service shall be clearly defined and includes supervision of both personnel performance and patient care.

(B) There shall be a written delineation of functions, qualifications, and patient care responsibilities for all categories of nursing personnel.

(C) Surgical technicians and licensed vocational nurses may be permitted to serve as the scrub nurse under the direct supervision of an RN; they shall not be permitted to function as circulating nurses in the operating rooms, except in ASCs where no general anesthesia is administered and when there is an adequate number of RNs immediately available for an emergency situation. Licensed vocational nurses and surgical technicians may assist in circulatory duties under the supervision of a qualified RN during general anesthesia cases.

(D) Nursing services shall be provided in accordance with current recognized standards or recommended practices.

(3) There shall be an adequate number of RNs on duty to meet the following minimum staff requirements: director of the department (or designee), and supervisory and staff personnel for each service area to assure the immediate availability of an RN for emergency care or for any patient when needed.

(A) An RN shall assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the preparation and qualifications of the nursing staff available.

**(B) There shall be other nursing personnel in sufficient numbers to provide nursing care not requiring the service of an RN.**

**(4) An RN qualified, at a minimum, with current certification in basic cardiac life support, shall be on duty and on the premises at all times whenever patients are present in the facility.**

**§135.15**

**(b) Additional staffing requirements.** In addition to meeting the requirements for nursing staff under subsection (a) of this section, facilities must comply with the following minimum staffing requirements.

**(1) Facilities that provide only topical anesthesia, local anesthesia and/or minimal sedation are required to have a second individual on duty on the premises who is trained and currently certified in basic cardiac life support until all patients have been discharged from the facility.**

**(2) Facilities that provide moderate sedation/analgesia are required to have the following additional staff:**

**(A) a second individual on duty on the premises who is trained and currently certified in basic cardiac life support until all patients have been discharged from the facility; and**

**(B) an individual trained and currently certified in advanced cardiac life support must be available until all patients have been discharged from the post anesthesia care unit.**

**(3) Facilities that provide deep sedation/analgesia, general anesthesia, and/or regional anesthesia must have the following additional staff:**

**(A) a second individual on duty on the premises who is trained and currently certified in basic cardiac life support until all patients have been discharged from the facility; and**

**(B) an individual who is trained and currently certified in advanced cardiac life support must be on duty on the premises and sufficiently free of other duties to enable the individual to respond rapidly to emergency situations until all patients have been discharged from the post anesthesia care unit.**

**§§135.18, 135.19**

Legend: (Proposed Amendments.)

Single Underline = Proposed new language

**[Bold Print and Brackets]** = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§135.18. Unlicensed Ambulatory Surgical Center.

(a) If the department **[director]** has reason to believe that a person or facility may be providing ambulatory surgical services without a license as required by the Act, the person or facility shall be so notified in writing by certified mail, return receipt requested, and shall submit to the department the following information within 20 days of receipt of the notice:

(1) - (3) (No change.)

(b) If the person or facility has submitted an application for a license, the application will be processed in accordance with §135.20 of this title (relating to Initial Application and Issuance of License **[for Initial Applicants]**).

(c) (No change.)

(d) If the person or facility submits sufficient documentation to establish that ambulatory surgical services are not provided, the department **[director]** shall so notify the person or facility in writing within 30 days that no license is required. If the documentation submitted is determined to be insufficient by the department **[director]**, the person or facility shall be so notified in writing and shall have 10 days to respond. Following receipt of the response, if any, the department **[director]** shall then notify the person or facility in writing within 10 days of the determination.

**[(e) If a person or facility fails to respond as required by subsections (a) and (d) of this section, the provisions of §135.24(e) and (g) of this title (relating to Denial, Suspension, or Revocation of License) will govern.]**

§135.19. Exemptions.

(a) - (b) (No change.)

(c) The department **[director]** shall evaluate the claim for exemption and notify the person or facility in writing of the proposed decision within 30 days following receipt of the claim for exemption.

(d) (No change.)

(e) If the claim for exemption is proposed to be denied, the person or facility so affected shall have the right to appeal the determination to the department **[director]** by written

**§§135.19, 135.20, 135.21**

letter with the reasons supporting exemption within 10 days following receipt of the proposed denial.

(f) –(g) (No change.)

**[(h) In the event that a person or facility does not comply as required by subsection (g) of this section, the provisions of §135.24(e) and (g) of this title (relating to Denial, Suspension, or Revocation of License) will govern.]**

§135.20. Initial Application and Issuance of License.

(a) (No change.)

(b) Upon written or verbal request, the department [**director**] shall furnish a person with an application form for an ASC license. The applicant shall submit to the department [**director**] a completed original application and the nonrefundable license fee.

(1) (No change.)

(2) Upon receipt of the application, the department [**director**] shall review the application to determine whether it is complete. All documents submitted to the department must be originals. The address provided on the application must be the address at which the ASC is operating.

(3) If the department [**director**] determines that the application for an unlicensed ASC is complete and correct, a representative of the department shall schedule a presurvey conference with the applicant in order to inform the applicant of the standards for the operation of the ASC. A presurvey conference, may at the department's discretion, be waived for an applicant of a licensed ASC for which a change of ownership is anticipated.

(4) (No change.)

(c) (No change.)

(d) Withdrawal of application. If an applicant decides not to continue the application process for a license the application may be withdrawn. The applicant shall submit a written request to withdraw to the department [**director**]. The department [**director**] shall acknowledge receipt of the request to withdraw.

(e) (No change.)

§135.21. Inspections.

(a) - (c) (No change.)

(d) The survey report form shall be submitted as follows.

**§§135.21, 135.22, 135.23**

(1) The surveyor shall submit the survey report to their supervisor **[the director]** for evaluation and decision.

(2) – (3) (No change.)

(4) If deficiencies are cited and the plan of correction is not acceptable, the department **[director]** will notify the applicant in writing and request that the plan of correction be resubmitted. Upon resubmission of the acceptable plan of correction, written notice will be sent to the applicant acknowledging same.

(5) – (7) (No change.)

**§135.22. Renewal of Annual License.**

(a) (No change.)

(b) Renewal license. The department shall issue a renewal license to an ASC that meets the minimum standards for a license set forth in these sections.

(1) The ASC shall submit the following to the department no later than 30 days prior to the expiration date of the license:

(A) – (C) (No change.)

(D) an annual events report in accordance with §135.27(b)(1) **[§135.28(b)(1)]** of this title (relating to Patient Safety Program); and

(E) a best practices report in accordance with §135.27(b)(2) of this title **[§135.28(b)(2)]**.

(2) - (4) (No change.)

(c) (No change.)

**§135.23. Conditions of Licensure **[Annual License]**.**

**(a) An ASC license is issued only for the premises and person or governmental unit named on the application.**

**(b) An ASC license is issued for a single physical location, and shall not include multiple buildings or offsite locations.**

**(c) Multiple ASCs may share a single building, provided that:**

**(1) each ASC is separately licensed; and**

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**(2) no part of the building may be dually licensed by more than one ASC.**

(d) [(a)] No license may be transferred or assigned from one person to another person. If a change of ownership of a licensed ASC is anticipated, in order to ensure continuity of patient services, the department shall be informed in writing and the applicant shall submit a license application and nonrefundable fee at least 30 days prior to the change of ownership of each ASC. The procedure shall be handled in accordance with §135.20 of this title (relating to Initial Application and Issuance of License [for Initial Applicants]), with the exception of the presurvey conference and the on-site inspection, unless deemed necessary by the department. A **[temporary]** license will be issued for the newly acquired ASC effective on the date the ownership changed. The previous license will be void on the date of acquisition.

(e) [(b)] No license may be transferred from one ASC location to another. If an ASC is relocating, the ASC shall complete and submit a license application and non-refundable fee at least 30 days prior to the relocation of the ASC. The procedure shall be handled in accordance with §135.20 of this title, with the exception of the presurvey conference, unless deemed necessary by the department. An initial license will be issued for the relocated ASC effective on the date the relocation occurred. The previous license will be void on the date of relocation.

(f) [(c)] Written notice to the department of any change in telephone number must be received within 30 days after the number has changed.

(g) [(d)] If the name of an ASC is changed, the department must be notified in writing within 30 days after the effective date of the name change.

§135.24. Enforcement.

(a) Reasons for enforcement action.

(1) The Department of State Health Services (department) may deny, suspend, or revoke an ASC's license in accordance with Health and Safety Code (HSC), §243.011 if the applicant or licensee:

(A) fails to comply with any provision of the Act;

(B) fails to comply with any provision of this chapter or any other applicable laws;

(C) fails to comply with a special license condition;

(D) fails to comply with an order of the commissioner or another enforcement procedure under the statute;

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(E) has a history of noncompliance with the rules adopted under this chapter relating to patient health, safety, and rights which reflects more than nominal noncompliance;

(F) has aided, committed, abetted or permitted the commission of an illegal act;

(G) fails to provide an adequate application or renewal information;

(H) fails to timely pay assessed administrative penalties in accordance with the Act;

(I) fails to comply with applicable requirements within a designated probation period;

(J) fails to submit an acceptable plan of correction for cited deficiencies;  
or

(K) if the facility is participating under Title XVIII, and the Centers for Medicare and Medicare Services terminates the ASC's Medicare provider agreement.

(2) The department may suspend or revoke an existing valid license or disqualify a person from receiving a license because of a person's conviction of a felony or misdemeanor if the crime directly relates to the duties and responsibilities of the ownership or operation of an ambulatory surgical center.

(A) In determining whether a criminal conviction directly relates, the department shall consider the provisions of Texas Occupations Code, Chapter 53.

(B) The following felonies and misdemeanors directly relate because these criminal offenses indicate an ability or a tendency for the person to be unable to own or operate an ambulatory surgical center:

(i) a misdemeanor violation of the statute;

(ii) a misdemeanor or felony involving moral turpitude;

(iii) a conviction relating to deceptive business practices;

(iv) a misdemeanor of practicing any health-related profession without a required license;

(v) a conviction under any federal or state law relating to drugs, dangerous drugs, or controlled substances;



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(vi) an offense under the Texas Penal Code (TPC), Title 5, involving a patient or a client of any health care facility, a home and community support services agency or a health care professional;

(vii) a misdemeanor or felony offense under various titles of the TPC, as follows:

(I) Title 5 concerning offenses against the person;

(II) Title 7 concerning offenses against property;

(III) Title 9 concerning offenses against public order and decency;

(IV) Title 10 concerning offenses against public health, safety, and morals; or

(V) Title 4 concerning offenses of attempting or conspiring to commit any of the offenses in this subsection; and

(viii) other misdemeanors and felonies which indicate an inability or tendency for the person to be unable to own or operate an ambulatory surgical center.

(C) Upon a licensee's felony conviction, felony probation revocation, revocation of parole, or revocation of mandatory supervision, the license shall be revoked.

**[(a) Denial, Suspension or Revocation of a License. The department has jurisdiction to enforce the Acts or Rules adopted under this chapter.]**

**[(1) The department may refuse to issue or renew a license for an ASC that does not participate under Title XVIII if the center:]**

**[(A) fails to comply with any provisions of the Act or these sections; or]**

**[(B) is not in compliance with minimum standards for licensure at least 30 days prior to the expiration date of the temporary or annual license.]**

**[(2) The department may suspend the license of an ASC for one or more of the following reasons:]**

**[(A) misstatement or concealment of a material fact on any documents required to be submitted to the department or required to be maintained by the ASC pursuant to the Act; or]**

**[(B) materially altering any license issued by the department.]**

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**[(3) The department may revoke the license of an ASC for one or more of the following reasons:]**

**[(A) an act has been committed by the ASC or its employees which affects the health and safety of a patient;]**

**[(B) if an ASC has been cited for deficiencies and fails to submit an acceptable plan of correction in accordance with these sections; or]**

**[(C) if an ASC has been cited for deficiencies and fails to timely comply with minimum standards for licensure within the dates designated in the plan of correction.]**

**[(4) The department shall refuse to issue or renew a license of an ASC that participates under Title XVIII, if the certifying body, Centers for Medicare and Medicaid Services, has terminated that ASC's provider agreement under Title XVIII.]**

**(3) [(5)]** If the department **[director]** proposes to deny, suspend, or revoke a license, the department **[director]** shall give the applicant written notification of the reasons for the proposed action and offer the applicant an opportunity for a hearing. The applicant may request a hearing within 30 days after the date the applicant receives notice. The request must be in writing and submitted to the department as instructed in the notice of violation letter **[director, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756]**. A hearing shall be conducted pursuant to the Government Code, Chapter 2001, Administrative Procedure Act, and §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures). If a hearing is not requested in writing within 30 days after receiving notice of the proposed action, the applicant is deemed to have waived the opportunity for a hearing and the proposed action shall be taken.

**(4) [(6)]** If the department finds that a violation of the standards or licensing requirements prescribed by the Act creates an immediate threat to the health and safety of patients of an ASC, the department may petition the district court for a temporary restraining order to restrain continuing violations.

**(5) [(7)]** The **[If the]** provisions of Texas Occupations Code, Chapter 53, Consequences of Criminal Conviction, apply to an ASC**[, any procedures covering the denial, suspension, or revocation of a license shall be governed by the provisions in those statutes]**.

**(6) [(8)]** If a person violates the licensing requirements or the standards prescribed by the Act, the department may petition the district court for an injunction to prohibit the person from continuing the violation or to restrain or prevent the establishment or operation of an ASC without a license issued under the Act.

(b) – (d) (No change.)

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§135.25. Complaints.

(a) (No change.)

(b) All licensed ambulatory surgical centers are required to provide the patient and his/her guardian at time of admission a written statement identifying the department as the responsible agency for ambulatory surgical centers complaint investigations. The statement shall inform persons to direct complaint to the [Texas] Department of State Health Services, Facility Licensing Group [**Health Facility Licensing and Compliance Division**], 1100 West 49th Street, Austin, Texas 78756, telephone (888) 973-0022. This information must also be prominently and conspicuously posted for display in an area of the facility that is readily available to patients, families and visitors. Complaints may be registered with the department by phone or in writing. A complainant may provide his/her name, address, and phone number to the department. Anonymous complaints may be registered. All complaints are confidential.

(c) – (e) (No change.)

## **§§135.26, 135.29**

Legend: (Proposed New Rule)

Regular Print = Proposed new language

### **§135.26. Reporting Requirements.**

(a) The ambulatory surgical center must make a report of the following incidents to the department. A written letter of explanation with supporting documents must be mailed to the department within 10 business days of the incident. The mailing address is Department of State Health Services, Facility Licensing Group, 1100 West 49th Street, Austin, Texas 78756.

(1) The death of a patient while under the care of the ASC;

(2) The transfer of a patient to a hospital;

(3) Patient development of complications within 24 hours of discharge from the ASC resulting in admission to a hospital; and

(4) A patient stay exceeding 23 hours.

(b) On an annual basis, the ASC must report the types and numbers of procedures performed and the average length of stay during the previous 12 month period. The report will be made using a form to be prescribed by the department.

(c) Any theft of drugs and/or diversion of controlled drugs shall be reported to the local police agency, the State Board of Pharmacy, the Texas Department of Public Safety, and/or the Drug Enforcement Administration, and the Department of State Health Services.

(d) An ASC that performs abortions must comply with the reporting requirements specified in the Texas Health and Safety Code, §245.011.

(e) Occurrences of fire in the ASC shall be reported as specified under §135.41(2) of this title (relating to Fire Prevention, Protection, and Safety) and §135.42(1)(F) of this title (relating to Handling and Storage of Gases, Anesthetics, and Flammable Liquids).

### **§135.29. Time Periods for Processing and Issuing a License.**

(a) General.

(1) The date a license application is received is the date the application reaches the Department of State Health Services (department).

(2) An application for an initial license is complete when the department has received, reviewed, and found acceptable the information described in §135.20 of this title (relating to Initial Application and Issuance of License).

### §135.29

(3) An application for an annual renewal license is complete when the department has received, reviewed and found acceptable the information described in §135.22 of this title (relating to Renewal of Annual License).

(b) Time Periods. An application from a facility for an initial license or a renewal license shall be processed in accordance with the following time periods.

(1) The first time period begins on the date the department receives the application and ends on the date the license is issued, or if the application is received incomplete, the period ends on the date the facility is issued a written notice that the application is incomplete. The written notice shall describe the specific information that is required before the application is considered complete. The first time period is 45 calendar days.

(2) The second time period begins on the date the last item necessary to complete the application is received and ends on the date the license is issued. The second time period is 45 calendar days.

(c) Reimbursement of fees.

(1) In the event the application is not processed in the time periods stated in subsection (b) of this section, the applicant has the right to request that the department reimburse in full the fee paid in that particular application process. If the department does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request will be denied.

(2) Good cause for exceeding the period established is considered to exist if:

(A) the number of applications for licenses to be processed exceeds by 15% or more the number processed in the same calendar quarter the preceding year;

(B) another public or private entity utilized in the application process caused the delay; or

(C) other conditions existed giving good cause for exceeding the established periods.

(d) Appeal. If the request for reimbursement as authorized by subsection (c) of this section is denied, the applicant may then appeal to the commissioner of health for a resolution of the dispute. The applicant shall give written notice to the commissioner requesting reimbursement of the fee paid because the application was not processed within the established time period. The department shall submit a written report of the facts related to the processing of the application and good cause for exceeding the established time periods. The commissioner will make the final decision and provide written notification of the decision to the applicant and the director.

(e) Hearings. If a hearing is proposed during the processing of the application, the hearing shall be conducted pursuant to the Texas Government Code, Chapter 2001, Administrative

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Procedure Act (APA), the hearing procedures of the State Office of Administrative Hearings (Texas Government Code, Chapter 2003 and Rules of Procedure, 1 Texas Administrative Code, Chapter 155).

**§§135.41, 135.42**

Legend: (Proposed Amendments.)

Single Underline = Proposed new language

**[Bold Print and Brackets]** = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§135.41 Fire Prevention, Protection, and Safety.

An ambulatory surgical center (ASC) shall comply with the provisions of this section with respect to fire prevention, protection, and safety.

(1) (No change.)

(2) Fire reporting. Except as required under §135.42(1)(F) of this title (relating to Handling and Storage of Gases, Anesthetics, and Flammable Liquids), an [An] ASC shall report all occurrences of fire in writing no later than 10 calendar days following the occurrence to the department in care of the Facility Licensing Group (FLG) [director, Health Facility Licensing and Compliance Division (HFLCD)], [Texas] Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756 or fax to (512) 834-4514. Any fire occurrence causing injury to a person shall be reported no later than the next business day to the department [director], FLG [HFLCD], by fax or overnight mail, to the address or fax number previously mentioned in this paragraph.

(3) – (12) (No change.)

§135.42. Handling and Storage of Gases, Anesthetics, and Flammable Liquids.

An ASC shall comply with the requirements of this section for handling and storage of gas, anesthetics, and flammable liquids.

(1) Flammable germicides. If flammable germicides, including alcohol-based products, are used for preoperative surgical skin preparation, the facility must: [Flammable germicides shall not be used for preoperative preparation of the surgical field.]

(A) use only self-contained, single-use, pre-measured applicators to apply the surgical skin preparations;

(B) follow all manufacturer product safety warnings and guidelines;

**(C) develop, implement and enforce written policies and procedures outlining the safety precautions required related to the use of the products, which, at a minimum, must include minimum drying times, prevention and management of product pooling, parameters related to draping and the use of ignition sources, staff responsibilities related to ensuring safe use of the product, and documentation requirements sufficient to evaluate compliance with the written policies and procedures;**

**§§135.42, 135.52**

**(D) ensure that all staff working in the surgical environment where flammable surgical skin preparation products are in use have received training on product safety and the facility policies and procedures related the use of the product;**

**(E) develop, implement and enforce an interdisciplinary team process for the investigation and analysis of all surgical suite fires and alleged violations of the policies; and**

**(F) provide a written report of all occurrences of surgical suite fires within two business days to the department in care of the Facility Licensing Group, and complete an investigation of the occurrence and develop and implement a corrective action plan within 30 days.**

(2) – (3) (No change.)

**§135.52. Construction Requirements for New Ambulatory Surgical Centers.**

(a) – (c) (No change.)

**(d) Spatial requirements.**

**(1) - (6) (No change.)**

(7) Preoperative patient holding room.

(A) General. A preoperative holding area shall be provided and arranged in a one-way traffic pattern so that patients entering from outside the surgical suite can change, gown, and move directly into the restricted corridor of the surgical suite. The holding area shall be separate from the post-operative recovery suite **[recovery]** and the restricted corridor.

**(B) (No change.)**

(C) Patient toilet. A toilet room with handicapped accessible water closet and hand washing facilities shall be provided. The toilet room may be shared with the post-operative recovery suite **[recovery room]**, if conveniently located to both.

(D) (No change.)

(8) (No change.)

(9) Post-operative recovery suite **[Recovery room]**.

(A) General. A post-operative recovery suite **[recovery room]** shall be distinct and separate from preoperative areas. The post-operative recovery suite **[recovery room]** shall be arranged to provide a one-way traffic pattern from the restricted surgical



corridor to the post-operative recovery suite [recovery] and then to the extended observation rooms [second stage recovery] or discharge.

(B) Post anesthesia care unit [Patient station(s)]. A minimum of one patient station per operating room, plus one additional station, shall be provided.

(i) - (ii) (No change.)

**[(C) Patient toilet. A toilet room with handicapped accessible water closet and hand washing facilities shall be provided. The toilet room may be shared with the preoperative patient holding area, if conveniently located to both.]**

(C) [(D)] Extended observation rooms [Second stage recovery]. Separate [A separate] supervised rooms [room] or areas [area] may be provided for patients who are sufficiently stabilized [able] to leave the post anesthesia care unit [recovery/post-anesthesia room], but require [need] additional time in the facility for observation or comfort measures prior to being discharged [for all vital signs to be stabilized to the point where the patient may leave the facility].

(i) When individual rooms are provided **[for second stage recovery]**, the rooms shall have an area of at least 60 square feet. When such rooms include a bed or recliner, a minimum clearance of three feet at the foot and on each side of the bed or recliner shall be provided.

(ii) When an open or ward area is provided **[for second stage recovery]**, the minimum clearance from the bed or recliner to the side wall may not be less than three feet; and a space of four feet shall be provided at the foot of each bed or recliner. The minimum clearance between beds or recliners may not be less than three feet.

(D) Patient toilet. A toilet room with handicapped accessible water closet and hand washing facilities shall be provided. The toilet room may be shared with the preoperative patient holding area, if conveniently located to both.

**(10) - (12) (No change.)**

(13) Surgical suite. The surgical suite shall be arranged to preclude unrelated traffic through the suite. The surgical suite shall contain at least one operating room and all surgical service areas required under subparagraph (B) of this paragraph.

(A) (No change.)

(B) Surgical service areas.

(i) Restricted corridor. The restricted corridor shall serve as the primary passageway for staff and patients within the surgical suite. The following rooms and areas when provided or required by NFPA 101 shall have direct access to the restricted corridor:

(I) - (II) (No change.)

**(III) post-operative recovery suite [recovery room];**

**(IV) - (XI) (No change.)**

**(ii) – (ix) (No change.)**

(14) Treatment room.

(A) A treatment room is not required, but when provided, it may be used only for minor procedures [**that use only local anesthetics**].

(B) If anesthesia is administered in the treatment room, the room must comply with NFPA requirements for an anesthetizing location.

(C) [(B)] The treatment room shall have a clear floor area of at least 100 square feet exclusive of fixed or moveable cabinets, counters, or shelves.

(D) [(C)] The treatment room shall contain an examination table, a counter for writing, and hand washing facilities.

**(15) - (16) (No change.)**

(e) Details.

(1) Corridors.

(A) (No change.)

(B) Communicating corridor. The communicating corridor shall be used to convey patients by stretcher, gurney, or bed.

(i) The communicating corridor shall link the preoperative holding area, operating room(s) [**rooms(s)**], and post-operative recovery suite [**recovery room(s)**], and shall be continuous to at least one exit.

(ii) (No change.)

(2) Doors and windows.

(A) - (B) (No change.)

(C) Patient access doors. The minimum width of doors for patient access to examination and consultation rooms shall be three feet. The minimum width of doors requiring access for beds and gurneys (preoperative holding area, operating room, post-operative recovery suite [**recovery room**]) shall be three feet eight inches.

(D) - (F) (No change.)

(3) - (4) (No change.)

(5) Hand washing facilities. Location and arrangement of fittings for hand washing facilities shall permit their proper use and operation. Hand washing fixtures with hands free controls shall be provided in each examination room, preoperative area, post-operative recovery suite **[recovery room]**, soiled utility room, fluoroscopy room, clean work room, and toilet room. Particular care shall be given to the clearances required for blade-type operating handles. Lavatories and hand washing facilities shall be securely anchored to withstand an applied vertical load of not less than 250 pounds on the front of the fixture. In addition to the specific areas noted, hand washing facilities shall be conveniently located for staff use in rooms and areas noted under spacial requirements in subsection (d) of this section and throughout the center where patient care services are provided.

(6) - (8) (No change.)

(f) (No change.)

**(g) Elevators. All buildings that have patient services located on other than the main entrance floor shall have electric or electrohydraulic elevators. The elevators shall be installed in sufficient quantity, capacity, and speed to ensure that the average interval of dispatch time will not exceed one minute, and average peak loading can be accommodated.**

(1) - (3) (No change.)

(4) Elevator car size.

(A) (No change.)

(B) When an operating room(s) is located on a different floor **[other]** than the preoperative area or the post-operative recovery suite, **[and recovery floors]** a hospital-type elevator shall be provided. Cars of hospital-type elevators shall be at least five feet eight inches wide by eight feet five inches deep.

(5) - (12) (No change.)

(h) Mechanical requirements. This subsection contains requirements for mechanical systems; air-conditioning, heating and ventilating systems; steam and hot and cold water systems; plumbing fixtures; piping systems; and thermal and acoustical insulation.

(1) - (4) (No change.)

(5) Heating, ventilating, and air conditioning (HVAC) systems.

(A) - (B) (No change.)

(C) Ventilation system requirements. All rooms and areas in the center shall have provision for positive ventilation. Fans serving exhaust systems shall be located at the discharge end and shall be conveniently accessible for service. Exhaust systems may be combined, unless otherwise noted, for efficient use of recovery devices required for energy conservation. The ventilation rates shown in Table 1 of §135.54(a) of this title shall be used only as minimum requirements since they do not preclude the use of higher rates that may be appropriate.

(i) Temperatures and humidities. The designed capacity of the systems shall be capable of providing the following ranges of temperatures and humidities.

(I) (No change.)

(II) Post-operative recovery suite [**Recovery room**]. The system serving the post-operative recovery suite [**recovery room**] shall be capable of maintaining a temperature of 75 degrees Fahrenheit and a relative humidity range between 45% and 60%.

(III) (No change.)

(ii) Thermometers and humidity gauges. Each operating room and post-operative recovery suite [**recovery room**] shall have temperature and humidity indicating devices mounted at eye level.

(iii) - (xii) (No change.)

(D) (No change.)

(6) - (11) (No change.)

(i) Electrical requirements. All electrical material and equipment, including conductors, controls, and signaling devices, shall be installed in compliance with applicable sections of the NFPA 70, "National Electrical Code," 1999 edition, §517-50; NFPA 99, Chapter 13; the requirements of this subsection; and as necessary to provide a complete electrical system. Electrical systems and components shall be listed by nationally recognized listing agencies as complying with available standards and shall be installed in accordance with the listings and manufacturer's instructions.

(1) - (11) (No change.)

(12) Receptacles. Only listed hospital grade grounding receptacles shall be used in the operating rooms and post-operative recovery suite [**post anesthesia recovery area**]. This does not apply to special purpose receptacles.

(A) – (H) (No change.)

(13) Equipment.

(A) The following shall be powered from the Type I essential electrical system in accordance with the requirements of NFPA 99, §3-4.2.2.3 when such a system is required for safe operation of the ASC referenced in paragraph (17) of this subsection.

(i) (No change.)

(ii) Ventilating system serving preoperative areas, operating rooms, and the post-operative recovery suite [**post anesthesia recovery rooms**] shall be connected to the equipment system in accordance with the requirements of NFPA 99, Chapter 3.

(B) Laser equipment shall be installed according to manufacturer recommendations and shall be registered with **[the Bureau of]** Radiation Control, Texas Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756.

(C) (No change.)

(14) - (15) (No change.)

(16) Nurses calling systems.

(A) (No change.)

(B) A staff emergency assistance calling system station shall be located in each operating room, treatment room, examination room, post-operative recovery and preoperative holding area to be used by staff to summon additional help in an emergency. Activation of the system shall sound an audible signal at a staffed location, indicate type and location of call on the system monitor and activate a distinct visible signal in the corridor at the door. Additional visible signals shall be installed at corridor intersections in multi-corridor facilities. Distinct visible and audible signals shall be activated in the clean workroom, in soiled workroom, and if provided, in the nourishment station.

(17) - (18) (No change.)